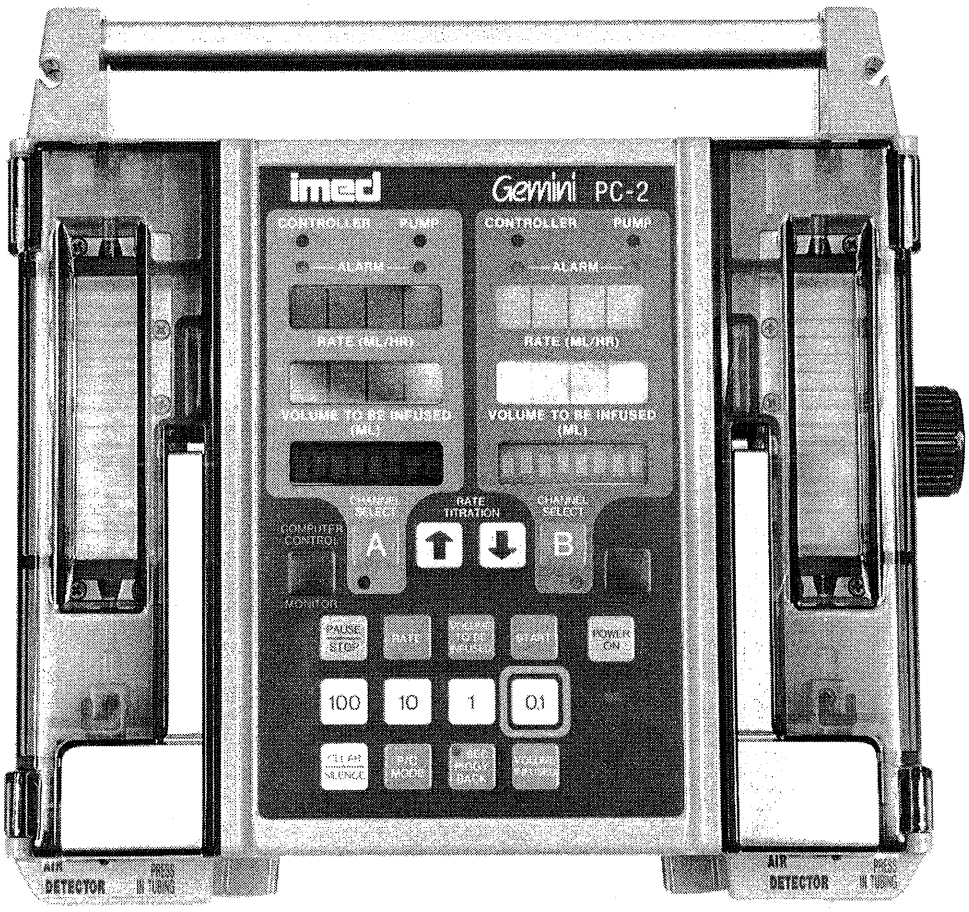
CE

imed®

2

OPERATOR'S MANUAL

220V



Gemini® PC-2® v3.44

VOLUMETRIC INFUSION PUMP/CONTROLLER

D

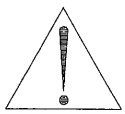
MACRO/MICRO RATES WITH TITRATION

14

15 JANUARY 1996

WARNING AND CAUTION NOTICES:

WARNING: TO PREVENT UNRESTRICTED FLOW, CLOSE ROLLER CLAMP WHEN FLO-STOP® IS OPEN.

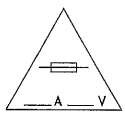


CAUTION: REFER TO MANUAL

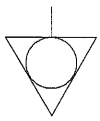
CLASS 1

TYPE CF (Equipment useable for direct cardiac applications)

ALTERNATING CURRENT



REPLACE FUSE ONLY WITH SAME TYPE AND RATING



EQUIPOTENTIAL GROUND POINT: IF THE INTEGRITY OF THE EQUIPOTENTIAL EARTH CONNECTION OR HOSPITAL EARTH SYSTEM IS IN QUESTION, OPERATE THE INSTRUMENT USING INTERNAL BATTERY POWER.

IPX1 **DRIP PROOF**

WARNING

If the PC-2 is dropped at any time, have the Biomedical Department perform a Periodic Safety Test (see Appendix) prior

COMPUTER CONTROL: A requirement for the approval of this instrument with the TGA is that the computer control mode be disabled. The use of hardware and software that controls flow rate via the communications interface is an unlawful use of this instrument. On individual application to the TGA, computer control could be authorized under the TGA's clinical trial notification or clinical trial exemption schemes.

RADIO FREQUENCY INTERFERENCE: Gemini products are tested to the requirements of HEW/FDA MDS-201-0004 and comply with the standards established for electrical-field, magnetic field and transient susceptibility. The HEW/FDA standard is 3 volts per metre. It is recommended that pumps should be positioned away from equipment which radiates high energy radio frequencies (e.g. Electro-surgical/cauterizing equipment, cellular telephones, etc.)

CAUTION: ONLY systems that have been qualified to IEC 601-1 standards should be connected to the PC-2's Nurse Call connector and the connection should ONLY be performed by qualified personnel.

P/N 1320-9249, Verif. 01
Revision 15 January 1996

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San Diego, CA 92131-1699 USA
(619) 566-9000

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Printed in USA
U.S. Patents 4,617,014; 4,689,043;
4,690,673; 4,725,205; 4,728,265; 4,764,166
Other Patents Pending

IMED Corporation
9775 Businesspark Avenue
San Diego, California 92131-1699 USA

8 January 1996

CE

DECLARATION OF CONFORMITY

IMED CORPORATION hereby declares that the **GEMINI PC-2® Medical Infusion Pump**, as designed for sale within the European Economic Area, complies with the provisions of Council Directive 89/336/EEC, the **Electromagnetic Compatibility (EMC) Directive.**

STANDARDS:

IEC 601-1-2 (EN60601-1-2); Medical Electrical Equipment, Part 1: General Requirements for Safety, 2. Collateral Standard: Electromagnetic Compatibility - Requirements and Tests, First Edition, 1993-04.

CISPR 11 (EN55011) Class B; Limits and Methods of Measurement of Electromagnetic Disturbance Characteristics of Industrial, Scientific and Medical (ISM) Radio-frequency Equipment, Second Edition, 1990-09.

David W. Meyers

David W. Meyers
Vice President, Quality

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NOTES

INTRODUCTION

The IMED® GEMINI PC-2® is a dual channel volumetric infusion pump and controller which provides accurate and automatic infusion of intravascular drugs, fluids, whole blood and packed red blood cells. The dual channels are independent, and the PC-2 may be operated as any combination of pump and/or controller.

Secondary (or piggyback) fluid may also be automatically infused at delivery rates and volumes independent of the primary infusion parameters, with automatic changeover to the primary infusion parameters when the secondary infusion is complete and when using a check valve administration set.

Computer operation is provided when the PC-2 is interfaced with a host computer. The technical data necessary to interface the PC-2 with a host computer is provided in the IMED C2 Programmer's Guide.

The PC-2 can be set to run in three different operating conditions:

- INDEPENDENT Operation - the PC-2 operates as a stand-alone instrument, with no computer interface.
- MONITOR Operation - the PC-2 controls the infusion and a host computer monitors instrument operation.
- COMPUTER CONTROL Operation - the PC-2 is under the control of a host computer, which sets the infusion parameters and monitors PC-2 operation. **NOTE: SEE COMPUTER CONTROL STATEMENT ON INSIDE OF FRONT COVER.**

To enhance safety and ease of operation, the PC-2 provides operator prompts and advisories, a full range of alarms and malfunction visual and audio alerts. Also provided is a tamper-resistant option which enables the user to lock out the front panel once infusion parameters have been entered and the infusion started.

The GEMINI PC-2 utilizes peristaltic action in both the pump and controller modes. When the PC-2 is operated in the controller mode, it senses the pressure created by the height of the fluid container and uses that pressure as the occlusion pressure limit. In the pump mode, the occlusion pressure limit is preset at approximately 10 psi (517 mm Hg / 69 kPa) for rates above 30 mL/hr. For rates 30 mL/hr and below, the occlusion pressure is rate-dependent to ensure rapid response to occlusions. The PC-2 may be locked into a rate-independent pump mode occlusion pressure of 10 psi (517 mm Hg / 69 kPa), if desired. However, this will result in significantly increased time to occlusion at rates below 30 mL/hr.

The infusion rate is selectable from 0.1 mL/hr to 999 mL/hr, and the volume to be infused (VTBI) from 0.1 mL to 9999 mL. The Rate Titration feature allows the selected channel's rate to be increased or decreased 1 mL/hr (MACRO mode) or 0.1 mL/hr (MICRO mode) with each single control press. Greater rate changes can be achieved by pressing and holding the ⌂ ⌄ controls until the desired rate is attained. Rates between 0.1 and 99.9 mL/hr may be selected in tenths of a milliliter increments. VTBIs between 0.1 and 999.9 mL may be selected in tenths of a milliliter increments if the rate is also in tenths.

Using a lockout feature, the Biomedical Engineering Department can configure the PC-2 to be either an exclusively MICRO delivery instrument, or an exclusively MACRO delivery instrument:

MICRO
- rates from 0.1 to 99.9 mL/hr (in 0.1 mL/hr increments)
- VTBIs from 0.1 to 999.9 mL (in 0.1 mL increments)

MACRO
- rates from 1 to 999 mL/hr (in 1 mL/hr increments)
- VTBIs from 1 to 9999 mL (in 1 mL increments)

MICRO/MACRO
- rates from 0.1 to 99.9 mL/hr in 0.1 mL/hr increments and rates from 100 to 999 mL/hr in 1 mL/hr increments
- VTBIs from 0.1 to 999.9 mL in 0.1 mL increments and VTBIs from 1000 to 9999 mL in 1 mL increments

The IMED Gemini PC-2 can be used *ONLY* with IMED GEMINI disposable administration sets. Primary sets are used for separate, independent primary infusions and for stand-alone gravity administration. Secondary infusions are possible using GEMINI check valve administration sets and appropriate IMED SECONDARY sets. GEMINI disposable sets utilize a unique clamping device, the Flo-Stop®, to prevent inadvertent free-flow when a set is removed from the PC-2.

The PC-2 has been designed to interface with optional accessory equipment, including an empty container detector (ECD) and a Nurse Call system. When an ECD is attached to the drip chamber of the primary administration set, the PC-2 can infuse the entire contents of the fluid container. The Nurse Call feature, when connected, activates an externally powered nurse call system when the PC-2 initiates any alarm, any malfunction, the "PRESS START" prompt, or the "INFUSION COMPLETE - KVO", "EMPTY CONTAINER - KVO", or "LOW BATTERY" advisories.

NOTES

Although the PC-2 is built and tested to exacting specifications, it is not intended to replace the supervision of IV infusions by medical personnel. The user should become thoroughly familiar with the features and operations of the PC-2 and exercise vigilance in its utilization.

IMED has available a PC-2 Maintenance Manual which includes circuit diagrams, component parts lists and descriptions, calibration and test procedures, and other technical information to assist qualified service personnel in repair and maintenance of the instrument's repairable components. Recommended periodic safety checks are in the APPENDIX of this document.

Safety checks and maintenance procedures are intended to be performed only by qualified personnel.

INSTALLATION PROCEDURES

The PC-2 has been thoroughly inspected before shipment from the factory to insure its mechanical and electrical integrity. However, handling in transit may cause visible or hidden damage. Therefore, prior to initial use, the PC-2 should be inspected at the user's facility.

Remove the unit from the shipping container and inspect it carefully for damage. Check that the doors operate freely. Check that the boots around the pumping mechanisms are not torn. Check the pole clamp for freedom of operation. Check the power cord for nicks and bent prongs on the connector. Check for any loose parts.

NOTE

If the instrument shows evidence of damage in transit, notify carrier's agent immediately. Do not return damaged equipment to the factory before the carrier's agent has authorized repairs.

Contact IMED for authorization to return equipment for repair, whether damage or malfunction is the responsibility of the carrier, or of IMED.

Performance Check

Refer to the PC-2 Maintenance Manual, IMED P/N 1320-9243-00

Battery Charge

The PC-2 is shipped with the battery in a charged condition. However, since a considerable time period could pass between shipment from the factory and initial use of the unit, perform a pre-operational battery charge. Connect the power cord to a 220/240 Volt receptacle. Allow the battery to charge for 24 hours. **Whenever possible, leave the power cord connected to the external power source while operating.**

RS-232 Connection/Computer Interface

Refer to the PC-2 Maintenance Manual and to the IMED C2 Communications Protocol Programmer's Guide, IMED P/N 1320-9004-01.

CAUTION

ONLY equipment that has been qualified to IEC 601-1 standards should be connected to the PC-2's RS-232-C Data Port and the connection should ONLY be performed by qualified personnel.

Nurse Call Connector

CAUTION

ONLY systems that have been qualified to IEC 601-1 standards should be connected to the PC-2's Nurse Call connector and the connection should ONLY be performed by qualified personnel.

OPERATING MODES: "P/C MODE", "MACRO", "MICRO","10 psi", "PANEL LOCKED", "SETUP" and "DIAGNOSTIC"

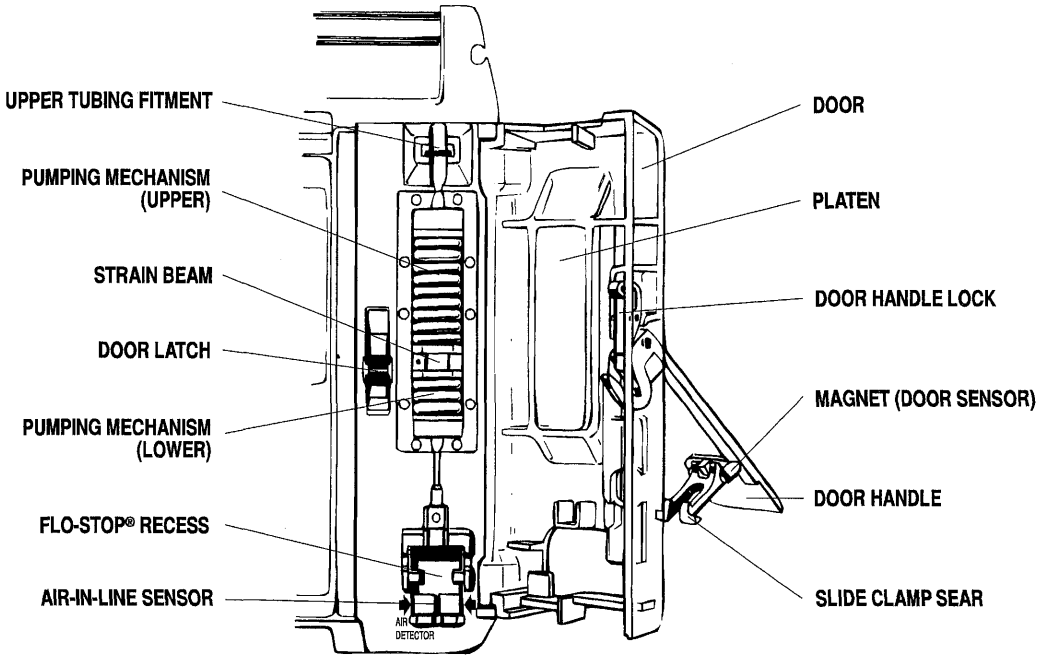
The Biomedical Engineering Department may lock the PC-2 into specific operating modes, which are indicated by scrolling advisories when the instrument is powered on. (See the Operator Information Display and Alarm Response Procedures section of this manual for descriptions of the advisories.) This manual describes proper operation when the instrument is locked into any of the various operating modes.

NOTE

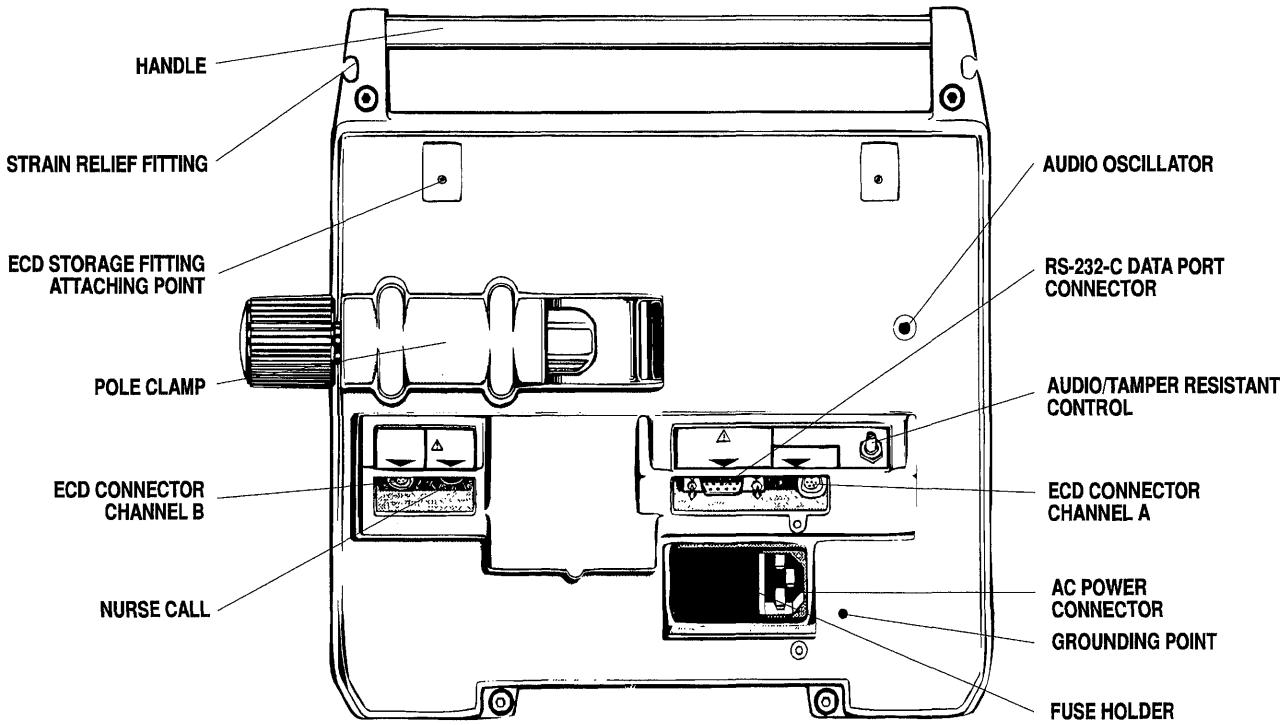
Prior to use, the user must determine whether the instrument configuration is appropriate for the prescribed infusion therapy.

For further information on these lock out procedures, direct inquiries to the Biomedical Engineering Department, or other personnel trained to setup specialized instrument configurations.

OPERATING FEATURES

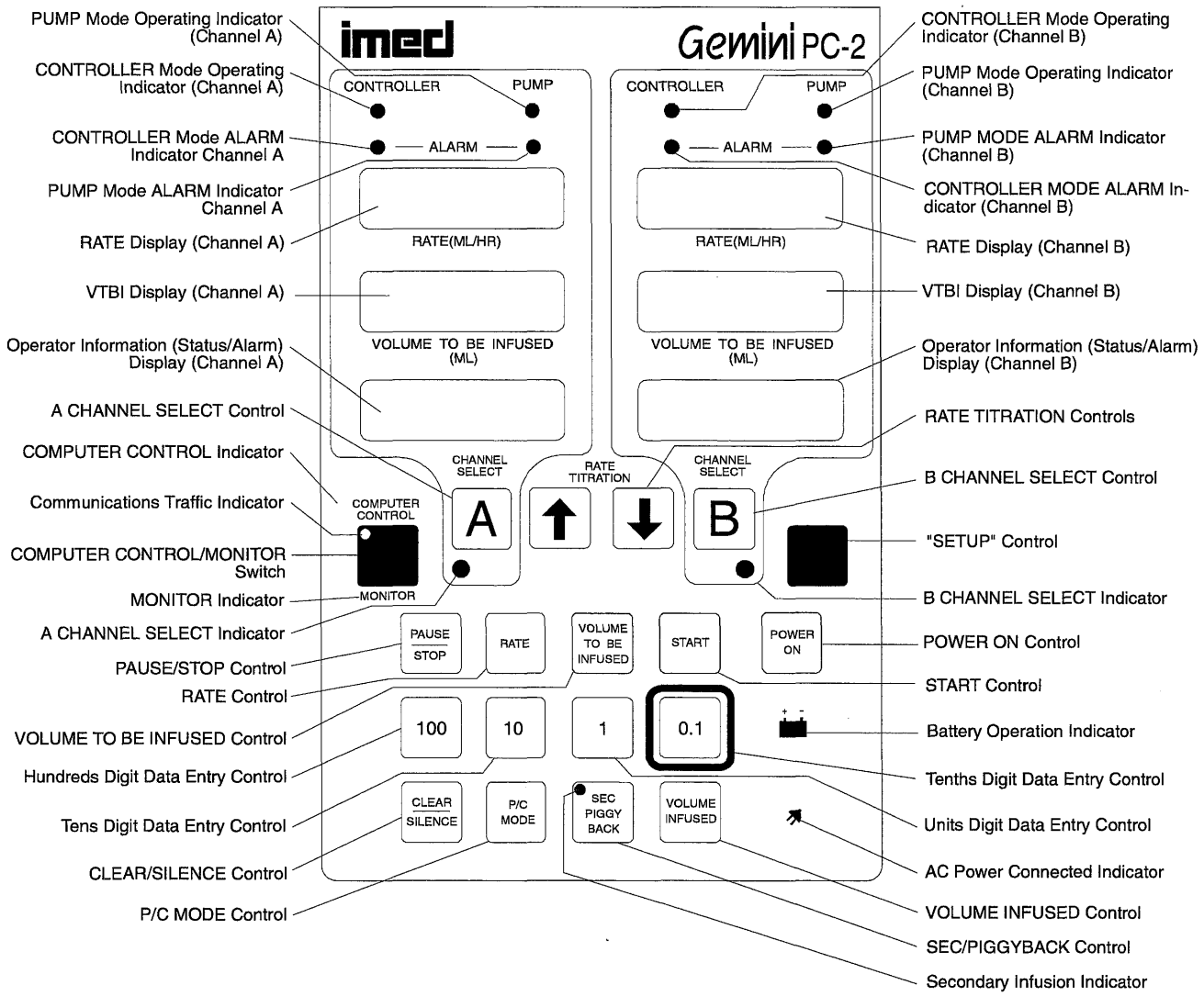


FRONT



REAR

FRONT PANEL CONTROLS AND INDICATORS



(Control and Indicator function are described by reference number)

DESCRIPTION OF CONTROLS AND INDICATORS

CONTROLLER and PUMP mode operating indicators - Channel A or B - when illuminated steadily, indicates the delivery mode selected for that channel; when flashing, indicates the respective channel is infusing.

CONTROLLER and PUMP mode ALARM indicators - Channel A or B - when flashing, indicates the respective channel is in an alarm condition.

RATE display - Channel A or B - displays primary and secondary rate infusion parameters, and other operator information.

VOLUME TO BE INFUSED (VTBI) display - Channel A or B - displays primary and secondary VTBI infusion parameters, and other operator information; flashes volume infused values for six times following press of VOLUME INFUSED control. Also used to recall current confirmed VTBI parameter.

Operator Information (Alarm/Status) display - Channel A or B - displays various advisory, prompt, alarm, malfunction, and communication status information. (Refer to OPERATOR INFORMATION DISPLAY AND ALARM RESPONSE PROCEDURES section of this manual for specific response procedures.)

CHANNEL SELECT A or B controls - when pressed once, selects the corresponding channel for primary or secondary infusion parameter entry and infusion setup; when pressed a second time, deselects the corresponding channel.

Channel Select A or B indicators - when illuminated, indicates that the corresponding channel is selected for infusion parameter entry and infusion setup.

COMPUTER CONTROL indicator - see Computer Control Statement on inside of front cover.

Communications Traffic indicator - illuminates when communication traffic is flowing over the RS-232-C data communication link; operable only during Monitor and Computer Control operation.

COMPUTER CONTROL/MONITOR control - see Computer Control Statement on inside of front cover.

MONITOR indicator - illuminates when interface cable is connected, and when in MONITOR mode.

PAUSE/STOP control - when pressed once, during a primary or secondary infusion, the infusion for the selected channel is stopped (After ≈2 minutes, the "PRESS START" visual and audio prompt begins.). When pressed a second time, it deselects the selected channel, and, if only that one channel has been running, it powers off the PC-2. If the other channel is also infusing, repeat to power off the PC-2. When pressed during a software-detected system malfunction, it powers off the PC-2.

RATE control - when pressed, allows the rate infusion parameter on the selected channel to be changed using the appropriate data entry controls. Also used to recall current confirmed Rate parameter.

DESCRIPTION OF CONTROLS AND INDICATORS (continued)

VOLUME TO BE INFUSED (VTBI) control - when pressed, allows the VTBI parameter on the selected channel to be changed using the appropriate data entry controls.

Hundreds & Thousands (100) Digit data entry control - when pressed, increments the hundreds digit of the rate infusion parameter on the selected channel (except when in MICRO delivery), or the hundreds and thousands digit of the VTBI infusion parameter on the selected channel and the selected parameter (thousands not functional in MICRO delivery). Upon reaching 9, display carries over to next higher digit.

Tens (10) Digit data entry control - when pressed, increments the tens digit of the rate or VTBI infusion parameter on the selected channel for the selected parameter. Display rolls over from 9 to 0.

Units (1) Digit data entry control - when pressed, increments the units digit of the rate or VTBI infusion parameter on the selected channel for the selected parameter. Display rolls over from 9 to 0.

Tenths (0.1) Digit data entry control - when pressed, increments the tenths digit of the rate or VTBI infusion parameter on the selected channel for the selected parameter (not functional in MACRO delivery). Display rolls over from 9 to 0.

CLEAR/SILENCE data entry control - when pressed following a press of the RATE or VTBI control, clears the rate or VTBI parameter on the selected channel; when pressed following a press of the Volume Infused control, clears the total and secondary volume infused displays for the selected channel; when pressed during an alarm or prompt, it silences the audio for ≈2 minutes.

P/C MODE control - when pressed with the P/C mode unlocked for the selected channel, alternately selects the PUMP delivery mode or the CONTROLLER delivery mode.

RATE TITRATION controls - when pressed, will increase or decrease the rate parameter 1 mL/hr (MACRO mode) or 0.1 mL/hr (MICRO mode) with each keypress or will scroll the rate up or down when pressed and held.

"SETUP" control - for use by biomedical and other specifically trained personnel to configure the instrument for specific operating modes.

POWER ON control - when pressed, applies electrical power to PC-2. If pressed during a hardware malfunction, silences audio alarm and turns off electrical power to all circuits.

START control - when pressed, starts the infusion on the selected channel.

Battery Operation indicator - when flashing, indicates the PC-2 is operating on battery power.

DESCRIPTION OF CONTROLS AND INDICATORS (continued)

AC Power Connected indicator - when illuminated, indicates the PC-2 is connected to an external power source.

VOLUME INFUSED control - when pressed once, will cause total volume infused to display for operating channels. A second press, while total volume infused is displaying, will cause the secondary volume infused to display for channel(s) operating in secondary. With a selected channel, the first press will display total volume infused and enable total and secondary volume infused registers for clearing.

SEC/PIGGYBACK control - when pressed, allows the entry of secondary infusion parameters on the selected channel; if pressed during a secondary infusion, viewing and changing of the primary infusion parameters can be performed on the selected channel.

Sec/Piggyback indicator - when flashing, indicates SEC/PIGGYBACK has been pressed; when illuminated, indicates a secondary infusion is in process.

Rear Panel **AUDIO/TAMPER-RESISTANT CONTROL** (on rear panel) - when rotated, varies the audio volume; when pressed, silences audio alarm for ≈2 minutes; when pressed and held for 3 seconds with the tamper-resistant feature enabled, will lock out all of the keypad controls except VOLUME INFUSED, SEC/PIGGYBACK and CLEAR/SILENCE; a repeat 3 second actuation will unlock the keypad controls.

ABBREVIATED SETUP AND OPERATING PROCEDURES

Introduction

The abbreviated procedures necessary to set up, start, and operate the PC-2 (independent operating condition) are described in the following sections.

These procedures are provided for use by personnel already familiar with the setup and operation of the PC-2. Refer to the detailed procedures and alarm responses in the appropriate sections of this manual.

To Set Up a Primary Infusion on Either Channel

1. Connect PC-2 to external AC power source.
2. Press POWER ON, and **check the advisories on the Operator Information Display to ensure the instrument is properly configured for the prescribed infusion therapy.**

WARNING

If the instrument alarms "HELP INTERNAL ERROR", DO NOT USE THE INSTRUMENT. Send it to the Biomedical Department for Inspection.

3. Remove set from package and close roller clamp.
4. Insert set spike into prepared fluid container and hang container a minimum of 24 inches above the PC-2.
5. Fill drip chamber to fill line (≈2/3 full).
6. Open roller clamp and prime set to remove all air.
7. Close roller clamp.
8. Open door and install the administration set, upper fitment first then the Flo-Stop®.
9. **Press the tubing into the Air-In-Line detector.**
10. Close door and open roller clamp.
11. Press appropriate CHANNEL SELECT.
12. Press P/C MODE to change delivery mode, if not locked out.
13. Press RATE; to change rate, use data entry controls.
14. Press VTBI; to change VTBI, use data entry controls.
15. Attach set to patient's indwelling venipuncture device.
16. Press START.

To Pause an Infusion

1. Press appropriate CHANNEL SELECT.
2. Press PAUSE/STOP once.
3. To resume infusion, press START.

To Stop a Primary Infusion

1. Press appropriate CHANNEL SELECT.
2. Press PAUSE/STOP twice.

To Change Rate or VTBI During Infusion

1. Press appropriate CHANNEL SELECT.
2. To change rate, press RATE and use data entry controls.
3. To change VTBI, press VTBI and use data entry controls.
4. Press START.

ABBREVIATED SETUP AND OPERATING PROCEDURES (continued)

To Rate Titrate

1. Press appropriate CHANNEL SELECT.
2. Press ⇧ or ⇩ control once to increment or decrement the rate parameter 1 mL/hr (MACRO) or 0.1 mL/hr (MICRO); press and hold the ⇧ or ⇩ control to scroll the rate up or down to desired setting.
3. Press START to confirm and change to the new rate.

To Change Delivery Mode During Infusion (P/C Mode control unlocked)

1. Press appropriate CHANNEL SELECT.
2. Press P/C MODE.
3. Press START.

To Restart an Infusion Following an "INFUSION COMPLETE-KVO" or "EMPTY CONTAINER-KVO" Advisory

1. Press appropriate CHANNEL SELECT.
2. Press VTBI and reset volume to be infused using data entry controls.
3. Refill drip chamber if necessary.
4. Press RATE and change if necessary.
5. Press START.

To View either Total and/or Secondary Volume Infused values for each Channel without selecting a channel

1. Press VOLUME INFUSED once for Total Volume Infused.
2. Press VOLUME INFUSED a second time for Secondary Volume Infused.

To View Total and/or Secondary Volume Infused on Selected Channel

1. Press appropriate CHANNEL SELECT.
2. Press VOLUME INFUSED once for Total Volume Infused.
3. Press VOLUME INFUSED a second time for Secondary Volume Infused.
4. Press START or CHANNEL SELECT.

To Clear Total Volume Infused and Secondary Volume Infused on Selected Channel

1. Press appropriate CHANNEL SELECT.
2. Press VOLUME INFUSED.
3. Press CLEAR/SILENCE while display is flashing.
4. Press START or CHANNEL SELECT.

To Set Up Secondary (Piggyback) Infusion With Dual Rates

1. Set up Primary infusion (using check valve set) as previously described.
2. Remove Secondary set from package and close roller clamp.
3. Insert set spike into prepared Secondary fluid container and hang container a minimum of 24 inches above the PC-2.
4. Fill drip chamber to the fill line (≈2/3 full).
5. Attach Secondary set needle.
6. Open Secondary clamp and prime set. Close clamp.

ABBREVIATED SETUP AND OPERATING PROCEDURES (continued)

7. Insert needle into upper injection site on Primary set.
8. Lower the Primary container using the hanger provided in the Secondary set package.
9. Press appropriate CHANNEL SELECT.
10. Press SEC/PIGGYBACK.
11. Press RATE and set Secondary rate using data entry controls.
12. Press VTBI and set Secondary volume to be infused using data entry controls.
13. Open the Secondary clamp.
14. Press START.

To View or Change Primary Infusion Parameters During a Secondary Infusion

1. Press appropriate CHANNEL SELECT.
2. Press SEC/PIGGYBACK and Primary parameters will display.
3. To change Primary rate, press RATE and use data entry controls during primary display.
4. To change Primary volume to be infused, press VTBI and use data entry controls during primary display.
5. Press appropriate CHANNEL SELECT.

To Stop a Secondary Infusion and Return to Primary Infusion

1. Press appropriate CHANNEL SELECT.
2. Press SEC/PIGGYBACK.
3. Close the Secondary clamp.
4. Press START during primary display.

To Infuse Using an Empty Container Detector (ECD)

1. Set up the Primary infusion.
2. Connect ECD plug to appropriate ECD receptacle on rear panel of instrument and attach ECD sensor to drip chamber of Primary set.
3. Set VTBI to "ALL" on appropriate channel by clearing the VTBI and pressing the 1 data entry control once, if in MACRO or MICRO/MACRO mode, or 0.1 control once, if in MICRO mode.
4. Press START.

To Clear Alarms

Refer to the OPERATOR INFORMATION DISPLAY AND ALARM RESPONSE PROCEDURES section.

To Power Off The PC-2

1. Press appropriate CHANNEL SELECT.
2. Press PAUSE/STOP twice.
3. Repeat sequence for other channel, if infusing.

INDEPENDENT SETUP AND OPERATING PROCEDURES

Introduction

The detailed procedures necessary to set up and operate the PC-2 on either channel in the independent operating condition are described in the following section. Procedures for computer operation are described in the "MONITOR or COMPUTER CONTROL Setup and Operating Procedures" section of this manual.

For operational procedures and alarm responses refer to the appropriate sections in this manual.

NOTE

Channels A and B may be operated independently and simultaneously to support a single patient by using either two infusion sites, or one infusion site and the lower injection site on the opposite channel's administration site.

To Set Up a Primary Infusion

1. Connect the PC-2 to an external AC power source using the power cord supplied by IMED.
2. Press the POWER ON control and **check the advisories on the Operator Information Display to ensure the instrument is configured for the prescribed infusion therapy.**
   - Verify that all indicators illuminate and all segments of the Channel A and B RATE and VTBI displays illuminate ("888.8") and both operator information displays show eight blocks of light.
   - "PC-2 V 3.xx" scrolls once across the operator information displays (3.xx represents the installed software version).
   - An audio tone sounds once.
   - The channel A and B operating indicators illuminate according to the previous delivery mode selection, either PUMP or CONTROLLER.
   - The rate and VTBI displays will show "- - - -" if the previous infusion was a MACRO delivery, or if the PC-2 is locked into MACRO delivery. The rate and VTBI displays will show "- - - -" if the previous infusion was a MICRO delivery, or if the PC-2 is locked into MICRO delivery.
   - "SET RATE" will scroll.
   - "MACRO" or "MICRO" will scroll if the PC-2 is locked into either one.
   - "10 PSI" will scroll, if the 10 psi mode is enabled.

WARNING

If the Instrument alarms "HELP INTERNAL ERROR", DO NOT USE THE INSTRUMENT. Send it to the Biomedical Department for inspection.

NOTE

If CHANNEL SELECT A or B control is not pressed within two minutes of pressing POWER ON, the PC-2 will automatically power down.

3. Open the GEMINI administration set package, remove set, and close the roller clamp.

4. Insert the set spike into the prepared fluid container and hang the container a minimum of 24 inches above the PC-2 following accepted hospital procedure.
5. Fill the drip chamber to the fill line (≈2/3 full).
6. Open the roller clamp slowly to prime the tubing and clear air from the injection sites and tubing fitments.
7. Close the roller clamp.
8. Open the door. Install the administration set pumping chamber by properly positioning the upper fitment into the upper fitment recess, and then inserting the Flo-Stop® fitment into the Flo-Stop recess below the pump mechanism, with the arrow pointing into the pump.
9. ***Press the tubing into the Air-In-Line detector.***
10. Close the door and open the roller clamp.
11. Press the appropriate CHANNEL SELECT control.
    - The channel select indicator illuminates.
    - The RATE and VTBI displays show "- - - -".
    - The "SELECT P/C MODE" prompt scrolls once, if P/C mode is unlocked. followed by a continuous scroll of "SET RATE" after ≈5 seconds.
    - An audio prompt begins after ≈12 seconds.
12. Press the P/C MODE control to change delivery mode to either Pump or Controller, if the P/C mode control is unlocked.
    - The appropriate channel operating indicator illuminates.
13. Set the rate and VTBI.
    a. Press the RATE control.
       - The last entered rate flashes.
    b. Use the appropriate data entry controls to change rate.
       - The new rate flashes.
       - "SET VTBI" scrolls.

NOTE

If the rate is ≥100 mL/hr, the tenths (0.1) control is not functional. If the rate is in tenths, the hundreds (100) control is not functional. If not locked into either MICRO or MACRO, pressing CLEAR/SILENCE will allow entry of either tenths or hundreds rate parameters. Both Rate and VTBI parameters must be in either MICRO or MACRO format.

    c. Press the VTBI control.
       - The last entered VTBI flashes.
    d. Use the appropriate data entry controls to change VTBI.
       - The new VTBI flashes.
       - The "PRESS START" prompt scrolls after 5 seconds.

NOTES

If the VTBI is greater than or equal to 1000 mL, the tenths (0.1) control is not functional. If not locked, pressing CLEAR/SILENCE will allow entry of either tenths or thousands. If the VTBI is greater than or equal to 1000 mL and a rate in tenths is selected, the VTBI will clear to a "0.0" when START is pressed.

A VTBI selection of "ALL" can only occur when the empty container detector (ECD) is attached. "ALL" will display after the VTBI has been cleared to "0" and the units (1) key is pressed once, if in MACRO or MICRO/MACRO mode, or the tenths (0.1) key, if in MICRO mode.

14. Attach the set to the patient's indwelling venipuncture device following accepted hospital procedure.
15. Press the START control.
    - The delivery mode and infusion parameters are entered.
    - The infusion is started.
    - The appropriate channel operating indicator flashes.

NOTES

Immediate air-in-line alarm after initial setup and operation may indicate that the administration set is not properly installed in the Air-In-Line detector.

If enabled, the tamper-resistant feature may be initiated at this point. Press and hold the AUDIO control (rear panel) for 3 seconds until an audio tone sounds. The front panel is now locked out, and "PANEL LOCKED" will scroll continuously. The only controls that are operable are CLEAR/SILENCE, SEC/PIGGYBACK, and VOLUME INFUSED (for viewing only). The infusion may not be altered in any way until the tamper-resistant feature is cancelled by repeating the 3 second AUDIO control press.

During infusion:
- The VTBI decrements.
- The volume infused increments (VOLUME INFUSED must be pressed to view).
- Various Advisories, Alarms, and Malfunctions may be displayed. Refer to the OPERATOR INFORMATION DISPLAY AND ALARM RESPONSE PROCEDURES section in this manual for an explanation and appropriate response.

Upon completion of the infusion:
- An audio prompt sounds.
- An "INFUSION COMPLETE-KVO" or "EMPTY CONTAINER-KVO" advisory scrolls.
- A 1 mL/hr or the set rate if <1.0 mL/hr KVO infusion is initiated and shown in the RATE display, and the channel operating indicator flashes.

To Pause an Infusion
1. Press the appropriate CHANNEL SELECT control.
2. Press the PAUSE/STOP control once.
    - The infusion stops.
    - The "PAUSE" advisory scrolls.
3. Press the START control to resume the infusion.

To Stop a Primary Infusion
1. Press the appropriate CHANNEL SELECT control.
2. Press the PAUSE /STOP control twice.
    - The infusion stops.
    - The channel operating indicator goes off.
    - All displays for the appropriate channel go off.
    - If this is the only channel in use, the PC-2 will automatically turn off.

To Change Rate or VTBI During Infusion

1. Press the appropriate CHANNEL SELECT control.
2. Press the RATE control to change rate.
   - The current rate flashes.
3. Use the appropriate data entry or the ⇧ ⇩ controls to change rate.
   - The new rate flashes.
4. Press the VTBI control to change VTBI.
   - The current decremented VTBI flashes.
5. Use the appropriate data entry controls to change VTBI.
   - The new VTBI flashes.
6. Press the START control.
   - The infusion is started at the new infusion parameters.
   - The new rate and VTBI displays.
   - The channel operating indicator flashes.

NOTE

If new rate and/or VTBI parameters have been selected, but not confirmed by pressing START or PAUSE; the currently confirmed parameters can be recalled by pressing Rate (VTBI), then pressing CLEAR/SILENCE and then pressing Rate (VTBI) again.

To Titrate RATE

1. Press the appropriate CHANNEL SELECT control.
2. Press the ⇧ or ⇩ control to change the rate parameter in 1 or 0.1 mL/hr increments
   or
   Press and hold the ⇧ or ⇩ control to scroll to a new rate parameter.
   - The new rate display will begin flashing ≈0.5 seconds after the last input.
   - After 5 seconds, the "PRESS START" prompt starts scrolling.
3. Press START control.
   - The new rate is confirmed and displays steadily.
   - The instrument infuses at the new rate.

To Change Delivery Mode During Infusion (P/C Mode control unlocked)

1. Press the appropriate CHANNEL SELECT control.
2. Press the P/C MODE control.
   - The channel operating indicator illuminates according to the new delivery mode selection.
   - The channel operating indicator for the active infusion continues to flash.
3. Press the START control.
   - The new delivery mode is entered, and the indicator begins to flash.
   - The infusion is started in the new delivery mode.

To Restart an Infusion Following an "INFUSION COMPLETE - KVO" or "EMPTY CONTAINER - KVO" Advisory

1. Press the appropriate CHANNEL SELECT control.
   - A "0", or the current decremented VTBI, or "ALL" flashes (depending upon original setup).
   - The original rate displays.

2. Press the VTBI control to change VTBI.
3. Use the appropriate data entry controls to change VTBI.
   - The new VTBI flashes.
4. Refill drip chamber, if necessary.
5. Press the RATE control to change rate, if necessary.
6. Use the appropriate data entry controls to change rate.
   - The new rate flashes.
7. Press the START control.
   - The new delivery mode or infusion parameters are entered and the infusion is started.

To View Total and/or Secondary Volume Infused on Both Channels Simultaneously

1. Press the VOLUME INFUSED control once.
   - The total volume infused for any channel(s) in use flashes in the appropriate VTBI display for six seconds.
   - The "TOTAL VOL INFUSED" advisory scrolls once across both channels simultaneously.
2. Press the VOLUME INFUSED control a second time.
   - The secondary volume infused for any channel(s) operating in secondary flashes in the respective VTBI display(s) for six seconds.
   - The "SEC VOL INFUSED" advisory scrolls once across both channels simultaneously.
   - The display(s) then reverts to previous status.

To View Total and/or Secondary Volume Infused on Selected Channel

1. Press the appropriate CHANNEL SELECT.
2. Press the VOLUME INFUSED control once.
   - The total volume infused flashes in the VTBI display for six seconds.
   - The "TOTAL VOL INFUSED" advisory will scroll once.
3. Press the VOLUME INFUSED control a second time.
   - The secondary volume infused flashes in the VTBI display for six seconds.
   - The "SEC VOL INFUSED" will scroll once.
   - The display then reverts to previous status.
4. Press the START or CHANNEL SELECT control.

To Clear Total and Secondary Volume Infused on Selected Channel

1. Press the appropriate CHANNEL SELECT.
2. Press the VOLUME INFUSED control once.
   - The total volume infused flashes in the VTBI display for six seconds.
   - The "TOTAL VOL INFUSED" advisory will scroll once.
3. Press CLEAR/SILENCE while the display is flashing to clear both the total and the secondary volume infused displays to "0".
4. Press the START or CHANNEL SELECT control.

NOTE

Volume Infused parameters cannot be cleared while displaying Secondary Volume Infused. Secondary Volume Infused automatically clears after changeover to Primary occurs.

To Set Up Secondary (Piggyback) Infusion With Dual Rates

NOTE

The PC-2 will only allow Secondary infusion parameters in the same delivery modes (MACRO/ MICRO and PUMP/CONTROLLER) as the Primary parameters.

1. Set up and start the Primary infusion (using a check valve administration set) as previously described.
   - The Secondary infusion may be set up prior to or after starting a Primary infusion.
2. Open the IMED SECONDARY administration set package, remove set, and close clamp.
3. Insert the set spike into the prepared fluid container and hang the Secondary container following accepted hospital procedure.
4. Fill the drip chamber to the fill line (≈2/3 full).
5. Attach the enclosed needle to the Secondary set.
6. Open Secondary clamp and prime the set. Close clamp.
7. Insert the Secondary set needle into the upper injection site on the Primary set.
8. Lower the Primary fluid container using the hanger provided with the Secondary set.
9. Press the appropriate CHANNEL SELECT control.
   - The primary infusion continues uninterrupted.
10. Press the SEC/PIGGYBACK control.
    - The Sec/Piggyback indicator flashes.
    - The RATE and VTBI displays show "SEC".
    - "SET RATE" begins scrolling.
11. Press the RATE control.
    - The last entered Secondary rate flashes.
12. Use the appropriate data entry controls to change Secondary rate.
    - The new Secondary rate flashes.
    - "SET VTBI" begins scrolling.
13. Press the VTBI control.
    - The last entered Secondary VTBI or the current decremented Secondary VTBI flashes.
14. Use the appropriate data entry controls to change Secondary VTBI.
    - The new Secondary VTBI flashes.

NOTES

"ALL" is not an allowable VTBI for a Secondary (Piggyback) infusion. Do not use an ECD on a Secondary administration set.

Verify that the Secondary VTBI setting does not exceed the contents of the Secondary fluid container.

15. Open the clamp on the Secondary set.
    - The Secondary fluid will begin to flow.

16. Press the START control.
    - The Secondary infusion is started at the infusion parameters entered.
    - A "SECONDARY" advisory scrolls.
    - The Sec/Piggyback indicator illuminates.

    During Secondary infusion:
    - The Secondary VTBI decrements.
    - Both the Secondary and the Total Volumes Infused increment (VOLUME INFUSED must be pressed to view).
    - Various Advisories, Alarms, and Malfunctions may be displayed. Refer to the OPERATOR INFORMATION DISPLAY AND ALARM RESPONSE PROCEDURES section in this manual for an explanation of and the response to these Advisories, Alarms, and Malfunctions.

    Upon completion of the Secondary infusion:
    - The audio tone sounds six times.
    - The PC-2 automatically switches over to the Primary infusion parameters.
    - The preset Primary rate and VTBI display.
    - The Sec/Piggyback indicator and the "SECONDARY" advisory cease.
    - "PRIMARY" will display unless PAUSE/STOP is pressed and then START is pressed.
    - The Secondary Volume Infused automatically clears.

NOTE

Actual changeover from the Secondary to the Primary IV solution is accomplished independently of pump/controller operation and occurs when the fluid level in the Secondary container drops to the same level as the fluid in the Primary administration set drip chamber.

To View or Change Primary Infusion Parameters During Secondary Infusion

1. Press the appropriate CHANNEL SELECT control.
    - The Secondary infusion continues uninterrupted.
2. Press the SEC/PIGGYBACK control.
    - The last entered Primary rate and VTBI display.
    - The "PRIMARY" and "SET RATE" prompts scroll immediately, followed by "PRESS START".
3. Press the RATE control to change Primary rate.
4. Use the appropriate data entry controls to change Primary rate.
    - The new Primary rate flashes.
5. Press the VTBI control to change Primary VTBI.
6. Use the appropriate data entry controls to change Primary VTBI.
    - The new Primary VTBI flashes.
7. Press the CHANNEL SELECT control.
    - The new Primary infusion parameters are entered and will begin upon completion of the Secondary infusion.

To Stop a Secondary Infusion and Return to the Primary Infusion

1. Press the appropriate CHANNEL SELECT control.
2. Press the SEC/PIGGYBACK control.

3. Close Secondary clamp.
4. Press the START control during the Primary display.
   - The Secondary infusion stops and the Primary infusion starts.
   - The Primary rate and VTBI display.
   - The "SECONDARY" advisory ceases.
   - The audio tone sounds six times.

To Infuse Using an Empty Container Detector (ECD)

1. Set up a Primary infusion on either channel.
2. Connect an ECD to the appropriate ECD connector on the rear panel of the PC-2.
   - The appropriate channel indicator LED on the ECD will illuminate.
3. Attach the ECD sensor to the drip chamber of the Primary set.
4. Set the Primary VTBI to "ALL" by clearing the VTBI to "0", and pressing the "1" data entry control once in MACRO or MICRO/MACRO mode or the "0.1" control in MICRO mode; or set a specific VTBI.
5. Press the START control.

When the ECD senses an empty container:

- An audio prompt sounds.
- The "EMPTY CONTAINER - KVO" advisory scrolls.
- A KVO infusion rate of 1 mL/hr, or the set Rate if <1.0 mL/hr, is initiated and shown in the RATE display.
- The channel operating indicator continues to flash.

To Clear Alarms

1. Check the operator information display to determine the type of alarm condition.
2. Refer to the OPERATOR INFORMATION DISPLAY AND ALARM RESPONSE PROCEDURES section in this manual for the proper procedures for responding to a specific alarm condition.

To Power Off the PC-2

1. Press the appropriate CHANNEL SELECT control.
2. Press the PAUSE/STOP control twice.
   - The infusion stops.
   - All displays for that channel cease.
3. Repeat steps 1 and 2 if both channels are infusing.

During the power off sequence:

- Channel A Operator Information Display shows "POWER".
- Channel B Operator Information Display shows "OFF 3", where "3" represents the count down to power off in seconds.
- The display counts down from "3" to "1". Upon reaching "1", the PC-2 automatically powers off.

NOTE

To interrupt the power off sequence, press the PAUSE/STOP control prior to the count-down timer in the operator information display reaching "1". To resume the infusion, select appropriate channel, confirm Rate and VTBI, then press START and verify that the channel operating indicator is flashing.

MONITOR OR COMPUTER CONTROL SETUP AND OPERATING PROCEDURES

Introduction

The steps necessary to operate the PC-2 in Monitor or Computer Control Operation are described in the following section.

CAUTION

ONLY equipment that has been qualified to IEC 601-1 standards should be connected to the PC-2's RS-232-C Data Port and the connection should ONLY be performed by qualified personnel.

NOTE

SEE COMPUTER CONTROL STATEMENT ON INSIDE OF FRONT COVER

To Establish PC-2/Host Computer Interface

1. Set computer communication parameters.

   NOTE

   Before the PC-2 can be used in the Monitor or Computer Control Operation conditions, the computer communication parameters must be set by hospital technical personnel, both in the host computer and in the PC-2. Thorough familiarity with independent operation of the PC-2 is a prerequisite for technical personnel responsible for configuring the pump/controller for remote operation. The procedures for setting the computer communication parameters for the PC-2 are provided in the PC-2 Maintenance Manual. The procedures for setting the computer communication parameters for the host computer are provided in the IMED C2 Programmer's Guide.

2. Connect the communication interface cable to the RS-232-C communication DATA PORT connector (rear panel) of the PC-2 and to the host computer.

   NOTE

   Before the PC-2 can be set up for either Monitor or Computer Control Operation, the communication interface cable must be connected to the RS-232-C communication DATA PORT connector on the rear panel of the PC-2. The technical data necessary to interface the host computer interface cable to the PC-2's RS-232-C Communication DATA PORT connector is provided in the PC-2 Maintenance Manual.

   When power is then applied to the PC-2's circuits, the MONITOR indicator will illuminate.

   a. **To Change PC-2 Operating Condition from Independent to Monitor**, connect the communication interface cable to the RS-232-C communication DATA PORT connector (rear panel) of the PC-2.
      - The MONITOR indicator illuminates.

   b. **To Change PC-2 Operating Condition from Monitor to Computer Control**, press the COMPUTER CONTROL/MONITOR control.
      - The COMPUTER CONTROL indicator flashes and the MONITOR indicator extinguishes.

- When 2-way communications are established and the host computer takes control, the COMPUTER CONTROL indicator illuminates.
- The host computer starts the infusion. (The infusion cannot be started from the PC-2 after the computer establishes control.)
- The PC-2 keypad is inoperative, except for the PAUSE and COMPUTER CONTROL/MONITOR controls.
- The channel operating indicator flashes according to the delivery mode selected.
- The communication traffic indicator flickers when communication between the host computer and the PC-2 is taking place.

c. **To Change PC-2 Operating Condition from Computer Control to Monitor**, press the COMPUTER CONTROL/MONITOR control.
   - The COMPUTER CONTROL indicator goes off and the MONITOR indicator illuminates.

d. **To Change PC-2 Operating Condition From Monitor to Independent**, disconnect the communication interface cable from the RS-232-C communication DATA PORT connector (rear panel) of the PC-2.
   - The MONITOR indicator extinguishes.

To Set Up a Primary Infusion

1. Connect the PC-2 to an external AC power source using the power cord supplied by IMED.
2. Press the POWER ON control and **check the advisories on the Operator Information Display to ensure the instrument is configured for the prescribed infusion therapy.**
   - Verify that all indicators illuminate and all segments of the Channel A and B RATE and VTBI displays illuminate ("888.8") and both operator information displays show eight blocks of light.
   - "PC-2 V3.xx" scrolls once across the operator information displays (3.xx represents the installed software version).
   - An audio tone sounds once.
   - The channel A operating indicator will illuminate according to the previous delivery mode selection, either PUMP or CONTROLLER. Press CHANNEL SELECT B to determine the channel B delivery mode selection.
   - The rate and VTBI displays will show "- - - -" if the previous infusion was a MACRO delivery, or if the PC-2 is locked into MACRO delivery. The rate and VTBI displays will show "- - - -" if the previous infusion was a MICRO delivery, or if the PC-2 is locked into the MICRO mode.
   - "SET RATE" will scroll.
   - "MACRO" or "MICRO" will scroll if the PC-2 is configured into the respective mode.
   - "10 PSI" will scroll, if enabled.

WARNING

If the instrument alarms "HELP INTERNAL ERROR", DO NOT USE THE INSTRUMENT. Send it to the Biomedical Department for inspection.

NOTE

If CHANNEL SELECT A or B control is not pressed within two minutes of pressing POWER ON, the PC-2 will automatically turn off.

3. Open the GEMINI administration set package, remove set, and close the roller clamp.
4. Insert the set spike into the prepared fluid container and hang the container a minimum of 24 inches above the PC-2 following accepted hospital procedure.
5. Fill the drip chamber to the fill line (≈2/3 full).
6. Open the roller clamp slowly to prime the tubing and clear air from the injection sites and tubing fitments.
7. Close the roller clamp.
8. Open the door. Install the administration set pumping chamber by properly positioning the upper fitment into the upper fitment recess, and then inserting the Flo-Stop fitment into the Flo-Stop recess below the pump mechanism, with the arrow pointing into the pump.
9. **Press the tubing into the Air-In-Line detector.**
10. Close the door and open the roller clamp.
11. Press the appropriate CHANNEL SELECT control.
    - The channel select indicator illuminates.
    - The RATE and VTBI displays show "- - - -".
    - The "SELECT P/C MODE" prompt scrolls once, if P/C mode is unlocked, followed by a continuous scroll of "SET RATE" after ≈5 seconds.
    - An audio prompt begins after ≈12 seconds.
12. Press the P/C MODE control to change delivery mode, if the P/C mode control is unlocked.
    - The appropriate delivery mode indicator illuminates.
13. If in MONITOR operation, set the rate and VTBI. (If in CONTROL operation, the rate and VTBI will be set by the host computer.)
    a. Press the RATE control.
       - The last entered rate flashes.
    b. Use the appropriate data entry controls to change rate.
       - The new rate flashes.
       - "SET VTBI" scrolls.

NOTE

If the rate is greater than or equal to 100 mL/hr, the tenths (0.1) control is not functional. If the rate is in tenths, the hundreds (100) control is not functional. If not locked, pressing CLEAR/SILENCE will allow entry of either tenths or hundreds rate parameters.

    c. Press the VTBI control.
       - The last entered VTBI flashes.
    d. Use the appropriate data entry controls to change VTBI.
       - The new VTBI flashes.
       - The "PRESS START" prompt scrolls after ≈5 seconds.

NOTES

If the VTBI is greater than or equal to 1000 mL, the tenths (0.1) control is not functional. If not locked, pressing CLEAR/SILENCE will allow entry of either tenths or thousands. If the VTBI is greater than or equal to 1000 mL and a rate in tenths is selected, the VTBI will clear to a "0.0" when START is pressed.

A VTBI selection of "ALL" can only occur when the empty container detector (ECD) is attached. "ALL" will display after the VTBI has been cleared to "0" and the "1" control is pressed once, if in MACRO or MICRO/MACRO; or the "0.1" control, if in MICRO.

14. Attach the set to the patient's indwelling venipuncture device following accepted hospital procedure.
15. **If in MONITOR operation**, press the START control to begin the infusion.
    - The delivery mode and infusion parameters are entered.
    - The infusion is started.
    - The channel operating indicator flashes according to the delivery mode selected.

    If in CONTROL operation, press the COMPUTER CONTROL/MONITOR switch.
    - The COMPUTER CONTROL indicator flashes and the MONITOR indicator goes off.
    - When a valid command is received by the PC-2 via the RS-232-C port, the COMPUTER CONTROL indicator illuminates.
    - The host computer starts the infusion. (An infusion cannot be started from the PC-2 while the COMPUTER CONTROL indicator is illuminated steadily.)

NOTE

Immediate air-in-line alarm after initial setup and operation may indicate that the administration set is not properly installed in the Air-In-Line detector.

During infusion:
- The VTBI decrements.
- The volume infused increments (VOLUME INFUSED must be pressed to view).
- Various Advisories, Alarms, and Malfunctions may be displayed. Refer to the OPERATOR INFORMATION DISPLAY AND ALARM RESPONSE PROCEDURES section in this manual for an explanation and appropriate response.
- The communication traffic indicator flickers when communication between the host computer and the pump/controller is active.

Upon completion of the infusion:
- An audio prompt sounds.
- An "INFUSION COMPLETE-KVO" or "EMPTY CONTAINER-KVO" advisory scrolls.
- A KVO infusion is initiated with the KVO rate shown in the RATE display, and the channel operating indicators continue to flash.

To Power Off the PC-2 in MONITOR Operation

1. Press the appropriate CHANNEL SELECT control.
2. Press the PAUSE/STOP control twice.
   - The infusion stops.
   - All displays for that channel cease.
3. Repeat steps 1 and 2 if both channels are infusing.

To Power Off the PC-2 in COMPUTER Operation

1. Press the COMPUTER CONTROL/MONITOR switch.
   - The COMPUTER CONTROL indicator turns off.
   - The MONITOR indicator illuminates.
2. Press the appropriate CHANNEL SELECT control.
3. Press the PAUSE/STOP control twice.
   - The infusion stops.
   - All displays for that channel cease.
4. Repeat steps 1 and 2 if both channels are infusing.

During the power off sequence:

- Channel A Operator Information Display shows "POWER".
- Channel B Operator Information Display shows "OFF 3", where "3" represents the count down to power off in seconds.
- The display counts down from "3" to "1". Upon reaching "1", the PC-2 automatically powers off.

NOTES

To interrupt the power off sequence, press the PAUSE/STOP control prior to the count-down timer in the operator information display reaching "1". To resume the infusion, press START and verify that the delivery mode indicator is flashing.

The operating procedures listed below are identical for both MONITOR operation and Independent operation. Refer to the Independent Setup section of this manual for the detailed descriptions.

These operating procedures during COMPUTER CONTROL operation are performed by the host computer, and are described in the IMED C2 Programmer's Guide, P/N 1320-9004-00.

To Pause an Infusion
To Stop a Primary Infusion
To Change Rate or VTBI During Infusion
To Change Delivery Mode During Infusion (P/C Mode control unlocked)
To Restart an Infusion Following an "INFUSION COMPLETE - KVO" or "EMPTY CONTAINER - KVO" Advisory
To View Total and/or Secondary Volume Infused on Both Channels Simultaneously
To View Total and/or Secondary Volume Infused on Selected Channel
To Clear Total and Secondary Volume Infused on Selected Channel
To Set Up Secondary (Piggyback) Infusion With Dual Rates
To View or Change Primary Infusion Parameters During a Secondary Infusion
To Stop a Secondary Infusion and Return to the Primary Infusion
To Infuse Using an Empty Container Detector (ECD)
To Clear Alarms

OPERATOR INFORMATION DISPLAY AND ALARM RESPONSE PROCEDURES

The Operator Information Display displays four types of information: advisories, prompts, alarms, and malfunctions.

The characteristics of the accompanying audio sounds are as follows:

Type	Sound	Notes
changeover	six short beeps	variable volume; can be silenced, and **disabled via the SETUP mode**
prompt	one short beep every two seconds	variable volume; can be silenced
key click	one short beep	variable volume; cannot be silenced
advisory	one short beep every fifteen seconds	variable volume; can be silenced
alarm	one long beep every 1.5 seconds	variable volume; can be silenced
malfunction	pairs of long beeps	fixed 75 decibel volume; cannot be silenced

An **ADVISORY** is a sequence of audio and/or visual signals to advise the user of the operating status of the PC-2. The audio may be silenced for ≈2 minutes by pressing the CLEAR/SILENCE control.

Advisory	Meaning	Response
SECONDARY Audio: changeover when SEC complete Visual: continuous scroll	Secondary infusion in progress.	None.
PRIMARY Audio: none Visual: continuous scroll	SEC/PIGGYBACK pressed while operating in Secondary, or automatic changeover from Secondary to Primary has taken place.	None. (Press START to clear advisory.)
SETUP Audio: prompt Visual: continuous scroll	Instrument powered in the SETUP mode	DO NOT USE ON PATIENT. Check with Biomedical Department.
INFUSION COMPLETE-KVO Audio: prompt Visual: continuous scroll	VTBI has been infused; PC-2 is infusing at KVO rate.	Turn off PC-2, or set up new infusion.

Advisory	Meaning	Response
EMPTY CONTAINER - KVO Audio: prompt Visual: continuous scroll	Empty container detected by ECD before programmed VTBI delivered, or when "ALL" has been used as the VTBI infusion parameter. PC-2 is infusing at KVO rate.	Replace IV container, turn off PC-2, or set up new infusion.
	ECD plugged into PC-2, but not attached to drip chamber.	Attach ECD to drip chamber.
LOW BATTERY Audio: prompt Visual: continuous scroll	Low battery threshold sensed, remaining battery operational life is limited.	Connect AC power cord to outlet; alarm will be silenced.
DIAGNOSTIC Audio: key click Visual: continuous scroll	Instrument powered up in the DIAGNOSTIC mode.	DO NOT USE ON PATIENT. Check with Biomedical Department.
PAUSE Audio: advisory, then prompt after 2 minutes Visual: continuous scroll	PAUSE/STOP control has been pressed once.	Press START control to resume infusion, or press PAUSE/STOP a second time to stop infusion.
POWER OFF Audio: none Visual: static display	PAUSE/STOP control has been pressed twice.	None.
10 PSI Audio: none Visual: intermittent scroll	Pump mode is locked into 10 (±2) psi occlusion pressure at all flow rates.	None. Time to occlusion at low rates will be significantly increased.
PANEL LOCKED Audio: key click Visual: continuous scroll	Audio control has been pressed and held for 3 seconds to initiate tamper-resistant feature.	None. Repeat to cancel tamper-resistance.
LOW FLOW Audio: advisory Visual: continuous scroll	In Controller mode, flow has slowed due to backpressure equalling container height. An occlusion alarm will occur within one minute.	Check tubing for restriction, raise container, press START, or change to pump delivery mode (if P/C Mode control unlocked).
TOTAL VOL INFUSED Audio: none Visual: single scroll	VOLUME INFUSED control pressed once.	None; numeric value in VTBI display is cumulative.
SEC VOL INFUSED Audio: none Visual: single scroll	VOLUME INFUSED control pressed twice while in Secondary.	None. Numeric value in VTBI display reflects volume of secondary.
MACRO Audio: none Visual: continuous scroll	Can only set up using MACRO parameters.	None; PC-2 is locked in MACRO configuration.
MICRO Audio: none Visual: continuous scroll	Can only set up using MICRO parameters.	None; PC-2 is locked in MICRO configuration.

A **PROMPT** is an audio and/or visual signal to the user to perform some action. The audio may be silenced for ≈2 minutes by pressing the CLEAR/SILENCE control.

Prompt	Meaning	Response
SELECT P/C MODE Audio: none Visual: one scroll	Begins following press of POWER ON and CHANNEL SELECT controls, if P/C Mode control is unlocked.	Select Pump or Controller delivery mode, as appropriate.
SET RATE Audio: prompt Visual: continuous scroll	Begins following press of POWER ON and CHANNEL SELECT controls, or if START control is pressed with rate set to "0".	Press RATE control and enter rate.
SET VTBI Audio: prompt Visual: continuous scroll	Begins following press of VTBI control, or if START control is pressed with VTBI set to "0".	Press VTBI control and enter VTBI.
PRESS START Audio: prompt Visual: continuous scroll	Begins ≈5 seconds after last press of data entry controls if neither parameter is zero, or ≈12 seconds after an alarm is cleared, or ≈2 minutes after PAUSE is pressed.	Press START control.
SELECT CHANNEL Audio: none Visual: scrolls three times	Begins when attempt is made to set parameters or start infusion prior to selecting a channel.	Press appropriate CHANNEL SELECT control.

An **ALARM** is an audio and visual signal to the user that a potentially unsafe condition is present. Immediate action is required. Except during a "FLO-STOP OPEN/CLOSE DOOR" condition, the audio may be silenced for ≈2 minutes by pressing the CLEAR/SILENCE control.

Alarm	Meaning	Response
CHECK ECD Audio: alarm Visual: continuous scroll Channel mode Alarm indicator: flashes	START control pressed with VTBI set to "ALL" and ECD not connected, or ECD has been disconnected during an "ALL" infusion, or ECD has failed. Infusion stops..	Connect or repair ECD, or set VTBI to a value other than "ALL", then press START control.
CHECK IV SET Audio: alarm Visual: continuous scroll Channel mode Alarm indicator: flashes	Administration set not properly installed. Infusion stops.	Close roller clamp, remove and re-install administration set, close door, open roller clamp.
CLOSE DOOR Audio: alarm Visual: continuous scroll Channel mode Alarm indicator: flashes	Door opened during an infusion. Infusion stops.	Close door, press appropriate CHANNEL SELECT control, then press START control.

Alarm	Meaning	Response
AIR-IN-LINE Audio: alarm Visual: continuous scroll Channel mode Alarm indicator: flashes	Air has been detected in set during an infusion. Infusion stops.	Ensure tubing is properly installed in air-in-line detector. If air is present, clear air from administration set. Press appropriate CHANNEL SELECT control, then press START control.
OCCLUDED PATIENT SIDE Audio: alarm Visual: continuous scroll Channel mode Alarm indicator: flashes	Increased backpressure sensed while infusing in the Pump delivery mode. Infusion on affected channel stops.	Clear occlusion, press appropriate CHANNEL SELECT control, then press START control.
OCCLUDED FLUID SIDE Audio: alarm Visual: continuous scroll Channel mode Alarm indicator: flashes	Upstream occlusion sensed while infusing in Pump delivery mode. Infusion on affected channel stops.	Clear occlusion in fluid side of administration set, press appropriate CHANNEL SELECT control, then press START control.
OCCLUDED Audio: alarm Visual: continuous scroll Channel mode Alarm indicator: flashes	Occlusion is detected in either fluid or patient side while infusing in Controller delivery mode. Infusion on affected channel stops.	Clear occlusion or raise the fluid container. Press the appropriate CHANNEL SELECT control, then press the START control. (If the occlusion recurs, open and close door. Press CHANNEL SELECT and START control).
PARTIAL OCCLUSION FLUID SIDE Audio: alarm Visual: continuous scroll Channel mode Alarm indicator: flashes	Partial upstream occlusion detected while infusing in Pump delivery mode. Infusion on affected channel stops.	Remove cause of reduced flow in fluid side of administration set, press appropriate CHANNEL SELECT control, then press START control.
"FLO-STOP" OPEN/ CLOSE DOOR Audio: alarm Visual: continuous scroll Channel mode Alarm indicator: flashes	Flo-Stop open (in free flow position) with door open.	Close roller clamp on set or close door and resume infusion by pressing appropriate CHANNEL SELECT control, then pressing START control. (If alarm occurs when the door is opened, replace PC-2 with operable unit.)
KVO COMM CABLE Audio: alarm Visual: continuous scroll Channel mode Alarm indicator: flashes	Communication interface cable is disconnected. Infusion(s) continue(s) at KVO rate.	Reconnect communication cable. Press COMPUTER CONTROL/MONITOR control. Restart infusion(s) from host computer.
KVO COMM TOUT Audio: alarm Visual: continuous scroll Channel mode Alarm indicator: flashes	Communication time-out has occurred. Infusion continues at KVO rate.	Press COMPUTER CONTROL/MONITOR control to change PC-2 operation to MONITOR.

Alarm	Meaning	Response
KVO Audio: alarm Visual: continuous scroll Channel mode Alarm indicator: flashes	A disconnected communications cable has been reconnected.	Press CHANNEL SELECT and START to restart the interrupted infusion(s). Press COMPUTER CONTROL/MONITOR to restore computer controlled operation.
	A communications timeout has been corrected.	Press COMPUTER CONTROL/MONITOR control. Restart programmed infusion(s) from host computer.

A **MALFUNCTION** is a signal to alert the operator that a failure has been detected. Immediate action is required. The audio cannot be silenced.

Malfunction	Meaning	Response
HELP INTERNAL ERROR Audio: malfunction Visual: continuous scroll and the malfunction code will display in the VTBI display Channel mode Alarm indicator: flashes	A software detected malfunction has occurred. Infusion on both channels stops.	Press PAUSE/STOP control once to turn off the PC-2. Replace the PC-2 with operable unit.

NOTE: If Malfunction Code 26 appears, immediately disconnect the AC power cord from the external power source.

HELP BATTERY Audio: malfunction Visual: continuous scroll and malfunction code "38" will display in the VTBI display Channel mode Alarm indicator: flashes	Low battery voltage detected. Infusions on both channels stop.	Connect AC power cord to power source. Press PAUSE/STOP control to turn off the PC-2. Press POWER ON, press CHANNEL SELECT, reenter rate and VTBI. Press START to resume the infusion(s).
(HARDWARE-DETECTED MALFUNCTION) Audio: malfunction Visual: none Channel mode Alarm indicator: flashes	A hardware detected malfunction has occurred. Infusion on both channels stops.	Ensure that the AC power cord is connected to an external power source. Press POWER ON control to reset the audio and turn off electrical power to the PC-2. (If audio persists, press POWER ON, then CLEAR/SILENCE. Perform normal power off procedures and replace PC-2 with operable unit.)

ADMINISTRATION SETS/ACCESSORIES

Use only IMED GEMINI adminstration sets with this instrument. Proper pump operation and accuracy cannot be guaranteed if other non-IMED infusion systems or accessories are connected to the IV sets. Connection of such systems or accessories may result in performance issues associated with flow accuracy, air-in-line, occlusion pressure measurements, or excessive nuisance alarms.

Proper operation and accuracy is guaranteed only if sets are changed according to individual administration set labeling. Fluid path is sterile, non-toxic, and nonpyrogenic if packaged set is intact. Sets are for single use only; do not resterilize.

The instrument should be serviced as recommended in the APPENDIX to ensure that accuracy is maintained.

2110 GEMINI 20 Vented/Nonvented Administration Set with 2 VersaSafe™ injection sites, 20 drops/mL

2120 GEMINI 20 Vented/Nonvented Check Valve Administration Set with 2 VersaSafe injection sites, 20 drops /mL

2126 GEMINI 20 Vented/Nonvented Administration Set with Check Valve and 3 VersaSafe injection sites, 20 drops/mL

2130 GEMINI 20 Vented/Nonvented Check Valve Administration Set with Check Valve and XL® 0.2 micron filter and 2 VersaSafe injection sites, 20 drops/mL

2140 GEMINI 20 Vented/Nonvented Administration Set with Metered Chamber and 3 VersaSafe injection sites, 20 drops/mL

2141 GEMINI 60 Vented/Nonvented Administration Set with Metered Chamber and 3 VersaSafe injection sites, 60 drops/mL

2177 GEMINI 12 Vented/Nonvented Y-type Blood/Solution Administration Set with 1 VersaSafe injection site, 12 drops/mL

2200 GEMINI 20 Vented/Nonvented Primary, 20 drops/mL

2210 GEMINI 20 Vented/Nonvented Primary with 2 injection sites, 20 drops/mL

2211 GEMINI 60 Vented/Nonvented Primary with 2 injection sites, 60 drops/mL

2214 GEMINI 20 Vented/Nonvented Primary with 15 micron filter, 2 injection sites, 20 drops/mL and multi-language labeling

2220 GEMINI 20 Vented/Nonvented Administration Set with Check Valve, 20 drops/mL

2226 GEMINI 20 Vented/Nonvented Administration Set with Check Valve and 3 injection sites, 20 drops/mL

2230 GEMINI 20 Vented/Nonvented Administration Set with Check Valve and XL 0.2 Micron Filter, 20 drops/mL

2240 GEMINI 20 Vented/Nonvented Metered Chamber with 3 injection sites, 20 drops/ml

2241 GEMINI 60 Vented/Nonvented Metered Chamber with 3 injection sites, 60 drops/mL

2255 GEMINI Vented/Nonvented Complimentary Short Set for use with #2906 Manifold

2260 GEMINI 20 Vented/Nonvented Primary for Nitroglycerin and Fat Emulsions, 20 drops/mL

2264 GEMINI 20 Vented Primary with XL 0.2 micron filter for use with Taxol, 20 drops/mL

2277 GEMINI 12 Nonvented Y-Type for Blood/Solution, 12 drops/mL

2280 GEMINI Primary Syringe Administration Set

2906 GEMINI 20 Vented/Nonvented Administration Set with Manifold below the instrument, 20 drops/mL

Accessories available for use with the PC-2:

1303 Communications Test Plug

1308 Empty Container Detector (for use with Non-Universal spike sets)

2285 Syringe Holder

SPECIFICATIONS

Detailed specifications will be available in the PC-2 Maintenance Manual. IMED reserves the right to change specifications without prior notice.

Operating Principle	Linear peristalsis
Infusion Accuracy	±5% at all available rates when using a #2210 administration set, 24" head height and H_2O
Mode of Operation	Continuous
Dimensions	10.8" x 11.8" x 7.3" (27.4 cm x 30.0 cm x 18.5 cm)
Weight	≈17.3 lbs (7.8 kg) including power cord
Power Requirements	220-240 VAC, ≈0.25A, 50/60 Hz, 3 wire, single phase
Fuse	T400A (two)
Rated Input Power	60VA
Maximum (nondestructive) voltage	264VAC, 50/60 Hz may be applied to any single input or output signal line without compromising patient or user safety.
Battery Operation	With a new, fully charged battery, approximately 5 hours with one channel operating at 125 mL/hr, or approximately 4 hours with two channels operating at 125 mL/hr before a "HELP BATTERY"
Battery Recharge	4 hours will recharge a new battery to the battery operation specification level (≈90% capacity). 10 hours will restore a new battery to a fully charged condition.
Electrical Leakage	Less than 100 microamps
Electrical Shock Protection	Class 1 type CF (Internally powered)
Level of Protection against Electrical Shock	Type CF equipment
Level of Protection against fluid ingress	IPX1
Rate Selections	0.1-999 mL/hr

Note: Recommended maximum rate in the Controller Mode is 500 mL/hr.

MICRO	0.1-99.9 mL/hr (in 0.1 mL/hr increments)
MACRO	1-999 mL/hr (in 1 mL/hr increments)

Volume-To-Be-Infused Selections	0.1-9999 mL, ALL
MICRO	0.1-999.9 mL (in 0.1 mL increments)
MACRO	1-9999 mL (in 1 mL increments)
KVO (Keep Vein Open) Rate	1 mL/hr if set rate is 1 mL/hr or above, or actual rate if set at 0.9 mL/hr or below
Occlusion Pressure	
Controller mode	Container height
Pump mode	10±2 psi (517±103 mm Hg / 69±14 kPa) for rates above 30 mL/hr. For rates of 30 mL/hr and below, the occlusion pressure will be less than 10 psi (517 mm Hg / 69 kPa), and is rate-dependent (unless locked into 10 psi (517 mm Hg / 69 kPa) for all rates.)
Maximum time to occlusion	5.25 minutes a 1.0 mL/hr; 10 seconds at 100 mL/hr (using a Gemini #2210 administration set, 24" head height and sterile water)
Bolus released after occlusion is cleared	56 microliters at 2.0 mL/hr: 250 microliters at 100 mL/hr (using a Gemini #2210 adminstration set, 24" head height and sterile water)
Advisories	SECONDARY, PRIMARY, INFUSION COMPLETE - KVO, EMPTY CONTAINER - KVO, LOW BATTERY, DIAGNOSTIC, SETUP, PAUSE, POWER OFF, 10 PSI, PANEL LOCKED, LOW FLOW, TOTAL VOL INFUSED, SEC VOL INFUSED, MACRO, MICRO.
Prompts	SELECT P/C MODE, SET RATE, SET VTBI, PRESS START, and CHANNEL SELECT.
Alarms	CHECK ECD, CHECK IV SET, CLOSE DOOR, AIR-IN-LINE, OCCLUDED PATIENT SIDE, OCCLUDED FLUID SIDE, OCCLUDED, PARTIAL OCCLUSION FLUID SIDE, FLO-STOP OPEN/CLOSE DOOR, KVO COMM CABLE, KVO COMM TOUT, and KVO.
Malfunctions	HELP INTERNAL ERROR, HELP BATTERY, and (HARDWARE-DETECTED MALFUNCTION)
Air-in-line Detection	Ultrasonic
Secondary (Piggyback)	Dual rate programmable
Nurse Call Feature	Activates an externally powered system when any alarm, malfunction, PRESS START prompt, or INFUSION COMPLETE - KVO, EMPTY CONTAINER - KVO, or LOW BATTERY advisory is issued by PC-2 software. Requires a DIN 6 pins at 240° plug (Switchcraft 12GM6M or equivalent) for proper mechanical interface.

See CAUTION on inside front cover and page 3

RS-232-C Communication Data Port Connector See CAUTION on inside front cover and page 3	Electronic Industry Association (EIA) Standard. Requires a standard 9-pin sub-miniature male mating connector with a standard screwlock backshell with jackscrews for proper mechanical interface.
Recommended Operating and Storage Ranges:	
Operating Temperature:	+5°C to +40°C
Storage Temperature:	-40°C to +70°C
Operating/Storage Humidity:	0% to 95% Relative @ +35°C

CLEANING

IMPORTANT INFORMATION FOR CLEANING YOUR GEMINI INFUSION PUMP

- As with all precision instruments, care and regular maintenance are necessary to ensure safe operation.
- Use only non-staining products recommended for use on plastic materials by their manufacturer, and use them in accordance with their instructions.
- Harsh cleaning materials, improper cleaning procedures, stronger concentrations and/or extended exposures can damage the instrument.
- **DO NOT attempt to sterilize the instrument with Ethylene Oxide gas, heat, steam, radiation, or autoclaving. To do so may damage the pump and void the warranty.**

CLEANING INSTRUCTIONS

CAUTION: Always unplug the power cord from the external AC power source before cleaning. Place the instrument in an upright position to prevent fluids from entering the bottom vents. Do not immerse or stand the instrument in any fluids. Only the external surfaces should be cleaned and disinfected.

Use a solution of mild soapy water, a 10% solution of household bleach, or isopropyl alcohol. Apply the solution with a soft lint free cloth, soft bristle brush, or cotton swab. Clean the Air-In-Line Detector groove, the elements behind the door, and the ECD's groove (if applicable), with cotton tipped swabs saturated with the solution. Disinfect using a non-staining, fungicidal, bacteriocidal, tuberculocidal solution.

Once the contamination has been removed, a cloth wet with fresh water should be used to rinse the entire pump to dilute and remove all residual cleaning/disinfecting solution. Repeat the process completely using another cloth moistened with fresh water. Following the fresh water rinses, thoroughly dry the instrument with a soft, lint-free cloth.

NOTE

Prior to connecting the power cord, ensure that the AC power connector is clean of any residue and dried thoroughly. Check the cord contacts for contamination; if contaminated, remove residue or replace the power cord.

APPENDIX

Periodic Safety Tests

Results of the following tests should be recorded on the log sheet provided at least every 12 months by qualified personnel to insure the safe operation of the infusion pump:

1. Visually inspect the instrument and any accessories for mechanical damage to the pumping mechanism, air-in-line detector, door, displays, keyboard, or any other areas which may impair operation.
2. Assure that the operating instructions, nameplate label, equipotentiality ground label, and other labels relevant to safety are present and legible.
3. Perform a grounding impedance test per VDE 0751, Part 1.
4. Check correct operation of all operational functions and alarms, described elsewhere in this manual.
5. Remove and check mains fuses for proper labeling and clean connections.
6. Measure the patient leakage current through the IV set per VDE 0751 and verify that it is less than 5μA.
7. Measure the instrument leakage current per VDE 0751, Part 1.
8. Test the infusion rate accuracy of the pump at 25°C ± 2°C using normal saline at a rate of 125 mL/hr in accordance with DIN 13253, Part 1, and verify that the error is less than 5% from the set rate value.
9. Test the air-in-line detector by injecting 2 mL of air with a syringe into an upper injection site while the pump is operating.
10. Perform a pump mode Output (occlusion) Pressure Test and confirm pressure limits of 10 ± 2 psi (517±103 mm Hg / 69±14 kPa).
11. Perform a Pump Pressure Test and confirm resultant pressure ≥17 psi (879 mm Hg / 117 kPa).
12. Battery Capacity Check. Refer to PC-2 Maintenance Manual, Section 5.8.3.2.

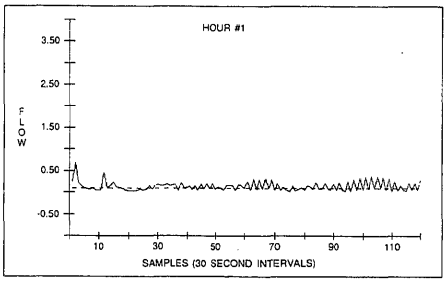
If the instrument fails to pass any of the above listed tests, it must be serviced or repaired by a qualified biomedical technician or an approved repair facility before any clinical use.

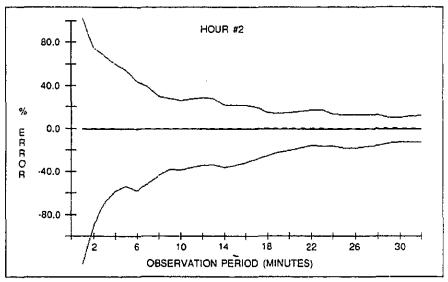
Safety Test Log

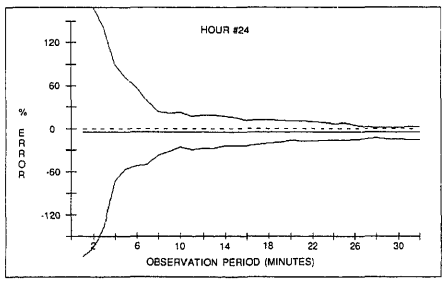
Safety Test	Test 1	Test 2	Test 3	Test 4	Test 5	Test 6	Test 7	Test 8
1 - Visual Inspection OK?								
2 - Labels OK?								
3 - Ground Impedance (in mΩ)								
4 - Operation & Alarms OK?								
5 - Fuses Correct?								
6 - Patient/IV leakage current in μA)								
7 - Instrument leakage current (in μA)								
8 - Infusion rate accuracy error (in %) at 125 mL/hr								
9 - Air-in-line Detector								
10- Output (Occlusion) Pressure Test								
11- Pump Pressure Test								
12- Battery Capacity Check								
Is instrument safe for operation?								
Signature of Safety Inspector								
Date of Testing								

PC-2 FLOW CONTINUITY CHARTS

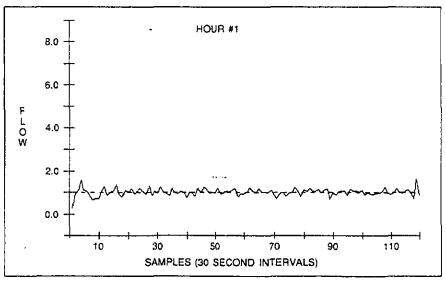
RATE: 0.1 ML/HR

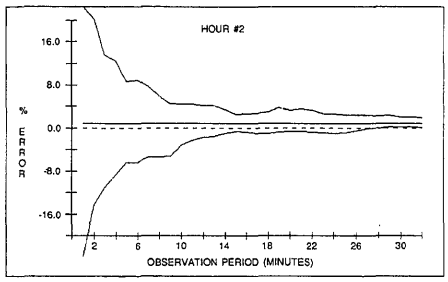


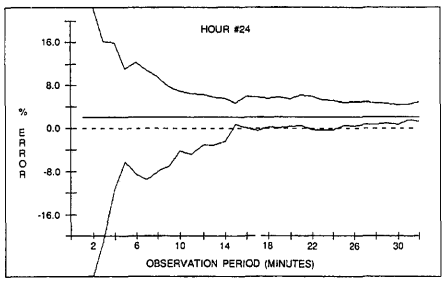




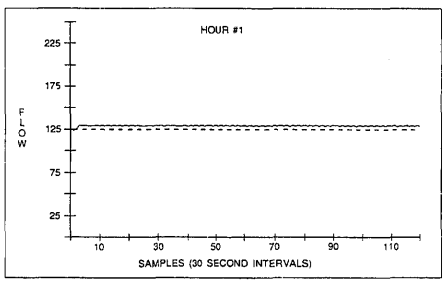
RATE: 1 ML/HR

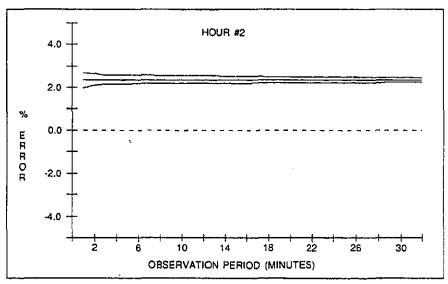


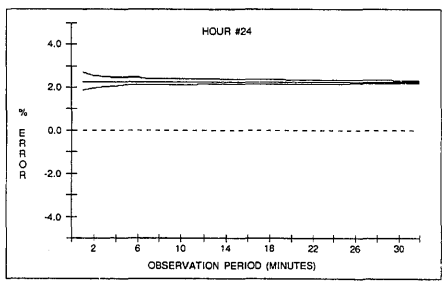




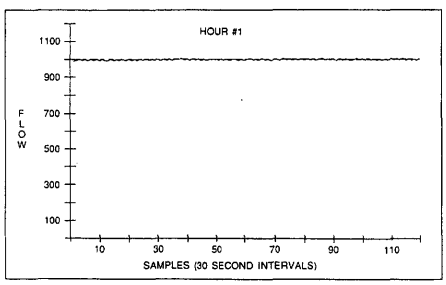
RATE: 125 ML/HR

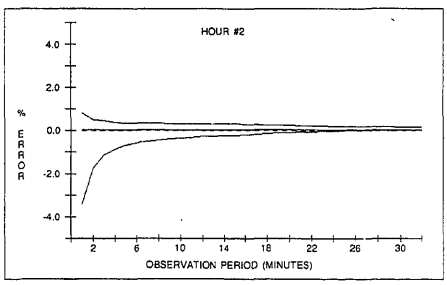


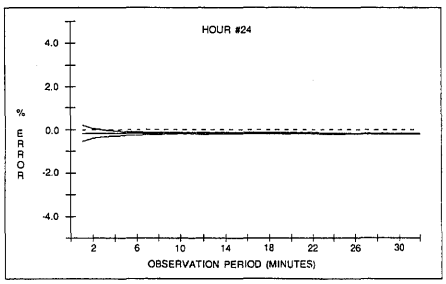




RATE: 999 ML/HR







Data is based on one sample for each rate tested.
Temperature: 23°C.
Headheight: 61 cm (24").
Fluid: water.

WARRANTY

IMED Corporation (hereinafter referred to as "IMED") warrants that each new IMED product is free from defects in material and workmanship, under normal use and service, for a period of one year from the date of purchase. A defective instrument should be returned to IMED properly packaged, with postage prepaid. IMED will then arrange for repairs or replacement within the terms of this warranty. Loss or damage in return shipment to IMED shall be at the purchaser's risk.

This warranty shall not apply to any IMED product which (1) has been repaired by anyone other than an authorized IMED representative, (2) has been altered in any way so as, in the judgment of IMED, to affect its stability, or reliability, (3) has been subject to misuse, negligence, or accident, (4) has had the serial number altered, effaced or removed, or (5) has been operated otherwise than in accordance with the instructions furnished by IMED.

Installation or use of component parts from sources other than IMED, without the express written consent of IMED, shall void the warranty given herein. In such event, product performance, reliability and liability, suits, claims, or damage arising therefrom shall be the sole responsibility of the user.

This warranty is in lieu of all other warranties, expressed or implied, and of all other obligations or liabilities on the part of IMED. THERE ARE NO WARRANTIES WHICH EXTEND BEYOND THE DESCRIPTION ON THE FACE HEREOF. IMED DISCLAIMS ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. IMED disclaims any liability for special, indirect, incidental, consequential, or exemplary damages. IMED neither assumes, nor authorizes any representative or other persons to assume for it, any other liability in connection with the sale of IMED products.

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